



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,019	06/28/2005	Akira Tsuji	Q88424	4031
23373 7590 04/15/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER				
PALENIK, JEFFREY T				
ART UNIT		PAPER NUMBER		
1615				
NOTIFICATION DATE		DELIVERY MODE		
04/15/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com
PPROCESSING@SUGHRUE.COM
USPTO@SUGHRUE.COM

Office Action Summary

Application No.

10/541,019

Applicant(s)

TSUJI ET AL.

Examiner

Jeffrey T. Palenik

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14, 17 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 14, 17 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Remarks filed, 19 January 2010 in the matter of Application N° 10/541,019. Said filings are entered on the record. The Examiner further acknowledges the following:

No claims have been added, amended or cancelled.

No new matter has been added.

Thus, claims 1-9, 14, 17 and 22 continue to represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statements (IDS) have been filed for consideration.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 20 July 2009 since the art which was previously cited continues to read on the amended/newly cited limitations.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 14, 17 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Timmins et al. (USPN 6,660,300).

The instantly amended claims 1 and 17 are drawn to a gastrointestinally-absorbed, pharmaceutical preparation comprising a mixture of the following components: 1) a compound recognized by a proton-coupled transporter, and 2) a pH-sensitive polymer. Claim 22 further limits the compositions of either claim 1 or 17 such that it narrows the amount of the pH-sensitive polymer to 10-20% based on the weight of the entire preparation.

The invention of Timmins is directed to biphasic-controlled release systems having both an inner solid particulate phase and an outer solid continuous phase. Said phases range in ratio from to one another from 0.5:1 (e.g. 1:2) to 4:1 (col. 9, lines 54-58). Both the inner and outer phases are expressly taught as comprising hydrophobic polymers preferably ranging from 35-60% by weight of the entire composition (col. 10, lines 24-34). Hydrophilic polymers which are expressly taught as being incorporated into the formulations include both methacrylic acid copolymers "L" and "S" or Eudragit L and Eudragit S (col. 10, lines 44-51). Regarding the

limitations of claim 22 wherein said range is narrowed to 10-20 wt% of the entire composition, the invention of Timmins also expressly teaches that the inner phase may comprise from about 15 to about 95% by weight in the form of hydrophobic polymers (col. 9, lines 59-67).

The dependent claims 2 and 3 further limit the type of transporter which is acted upon within the body. The specific types of transporters which are acted upon are: a peptide transporter (claim 4), a monocarboxylic acid transporter (claim 6) and an amino acid transporter transporting D-cycloserine (claim 8). Those types of or particular compounds which act on the transporters of claims 4, 6 and 8, are respectively recited in claims 5, 7 and 9.

Regarding the forgoing limitations for the compounds which act upon particular transporters, Timmins expressly teaches that numerous compounds may be delivered by the biphasic composition. Many different types of peptides are taught, including those which comprise amino acids such as proline and glycine (col. 17, line 28 to col. 18, line 47). Other non-peptide forms of active agents are taught such as captopril, a known acetylcholinesterase inhibitor (col. 18, lines 53-55). The forgoing agents which are taught represent examples of those compounds which are recited in both claims 5 and 9. Compounds which are expressly taught by Timmins and which are recited include those such as salicylic acid (e.g. aspirin and *p*-aminosalicylic acid) and nicotinic acid (col. 15, lines 6 and 19-20).

Claim 14 recites that the composition of claim 1 is an oral dosage form. Oral dosage forms are taught throughout the entire invention to Timmins (see for example the Abstract).

Thus, it would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made to have prepared the mixed composition as instantly claimed under the

guidance of the practiced invention of Timmins et al. The ordinarily skilled artisan would have been highly motivated to do so and would have had an equally high expectation of successfully arriving at the instantly claimed release composition, particularly since Timmins expressly teaches or suggests each of the above limitations. Of particular note, is that Timmins teaches that the active compound, which is released to the target transporters, is mixed into the formulation with particles of hydrophobic polymers, rather than being coated by a film of said polymers. Since this key distinction in Applicants' invention is met by the art, it is the conclusion of the Examiner that Applicants' invention as a whole would have been *prima facie* obvious at the time the invention was made, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-9, 14, 17 and 22 under 35 USC 103(a) as being unpatentable over the teachings of Timmins et al. have been fully considered but they are not persuasive.

Applicants allege that the reference "fails to disclose a proton-coupled transporter and a pH-sensitive polymer as recited in claim 1" and further that though "Timmins exemplifies Eudragit as a hydrophobic polymer ... this does not meet the requirement of a pH-sensitive polymer as recited in the presently claimed invention".

In response, the Examiner respectfully disagrees, particularly in light of the later recitation within the same claim which further limits said pH-sensitive polymer to such polymer embodiments as methacrylic acid copolymer L and/or methacrylic acid copolymer S. Furthermore, the limitation is interpreted in light of Applicants' instant disclosure, which states

the trademarked version of the recited copolymers, namely Eudragit® L and S blends. Both are expressly taught by the reference as polymers which are admixed with the active ingredient.

Applicants also traverse the rejection on the grounds that “Timmins fails to disclose that the amount of pH-sensitive polymer is 5 to 40 wt% based on the weight of the entire pharmaceutical preparation.”

In response, the Examiner respectfully disagrees and maintains that teaches that the pharmaceutical formulation will have a total polymer extended release content (i.e. hydrophilic and/or hydrophobic polymers in the inner and outer phases) ranging as broadly as about 25 wt% to about 75 wt% and most preferably range as narrowly as about 35-60 wt% based on the total weight of the pharmaceutical composition. In light of MPEP §2144.05, “where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists”. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990)

Lastly, Applicants’ remarks concerning the limitations of claim 22 are, in part, unpersuasive due to an admitted typographical error on the part of the Examiner. Said typo incorrectly conveyed the amount of hydrophobic polymer which may appear in the core with the active ingredient. Said amount is taught by Timmins as ranging as broadly as about 5 to about 95% by weight and preferably from about 7 to about 85% by weight being based on the weight of the inner solid particulate phase (col. 9, lines 59-67) [*emphasis added to reflect corrected typo*]. Thus, again, in light of MPEP §2144.05, the limitations of the instant claim 22 are met and rendered *prima facie* obvious by the art of record.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

All claims under consideration remain rejected; no claims are allowed.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615